A WRAP

Field of the Invention

The present invention relates to a wrap for securing about a blood vessel, and in particular for holding a vessel deformer adjacent an arterial vessel.

The invention has been primarily developed for use in securing the inflatable balloon or chamber of an implantable counter-pulsation heart assist device against the ascending aorta and will be described hereinafter with reference to this application.

Background of the Invention

The Applicant's International PCT Patent Application Nos. PCT/AU00/00654 and PCT/AU01/01187 disclose heart assist devices, systems and methods. More particularly, these specifications disclose vessel deformers in the form of inflatable balloon or chambers which form part of implantable counter-pulsation heart assist devices. The balloon or chambers are cyclically inflated and deflated and used to compress the patient's ascending aorta during diastole and release the compression during systole.

The balloon or chamber are generally secured to the aorta by a substantially non-elastic wrap or sheath, which is secured around a section of the aorta with the balloon or chamber therebetween. For the heart assist device to function efficiently, it is necessary that the wrap be a snug fit around the aorta when the balloon or chamber is deflated.

Hitherto, wraps have been manufactured from a length of substantially inflexible woven polyester material. The disadvantage of known wraps will be described with reference to Fig. 3 which shows a section of aorta 10 encased by a known wrap 12. If the wrap 12 is over-tightened (as shown), its sides cause a sharp depression or kink in the aorta 10, in the regions indicated by the reference numeral 14. This can also occur due to the aorta 10 enlarging slightly as the patient recovers or with age. This depression/kinking places a higher strain on the wall of the aorta 10 and can damage same. Also, the kink in the internal wall of the aorta 10 induces turbulence in the blood flow, which increases the likelihood of plaque formation.

Wrapping a curved vessel with a flat straight piece of fabric also leads to bunching or folding of the fabric. This is undesirable as it encourages secondary growth or potential infection in the bunched/folded region and results in uneven load distribution.

It is also known to place static wraps around blood vessels, for instance to reinforce vessels suffering from aneurysmal disease.

Any aortic compliance may be lost by placement of non-elastic or non shape-changing wrap, which may reduce the natural advantage of aortic compliance on cardiac function.

It is an object of the present invention to provide a wrap that substantially overcome or at least ameliorate one or more of the above disadvantages.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a wrap for securing about a blood vessel by encasing a section of the vessel, the wrap being of thin flexible construction having two ends and two sides. It is preferable that the wrap is more elastic or stretchable at, near, or along at least some of its sides compared to at, near, or along its centre, to provide strain relief from wrapped to unwrapped aorta.

It is preferable that the wrap is not inelastic, and that loss of aortic compliance is minimised, or in fact enhanced.

In a second aspect, the present invention provides a wrap for securing about a blood vessel by encasing a section of the vessel, the wrap being of thin flexible construction having two ends and two sides and being adapted to apply, in use, less compressive force at, near, or along at least some of its sides compared to at, near, or along its centre.

The wrap is preferably adapted for securing a vessel deformer adjacent the vessel, by sandwiching the deformer between the vessel and the wrap. The vessel deformer is preferably part of an implantable counter-pulsation heart assist device and most preferably is in the form of an inflatable balloon or chamber. The wrap is preferably adapted to secure the inflatable balloon or chamber against an aorta, most preferably the ascending aorta.

The wrap is preferably of woven or knitted construction, or a combination, and made of material such as polyester or PET (polyethylene terepthalate).

In one form, the wrap has slits along some of its sides, most preferably a series of spaced part slits that are normal to the direction of the sides. The slits make those parts of the sides more elastic or stretchable than the centre of the wrap.

In another form, the wrap has warp fibres at, near, or along its sides that are more elastic than the warp fibres at, near, or along its centre. In this form, the warp fibres, near

or along its sides are preferably crimped and the warp fibres at, near, or along its centre are preferably un-crimped or less crimped.

In another form, the wrap includes a strip of substantially centrally placed material, that has a tensile strength greater than that of the rest of the wrap.

In another form, the woven fabric may be cut on the bias to allow a more conformal wrap and with some improved elasticity along the edge areas of the wrap.

The two sides of the wrap can be of similar, or differing, elasticity or stretchability to each other. In the case of differing, the more elastic or stretchable side is positioned closer to the heart, as this is where there is greater movement.

In a yet further form, the wrap is thinner at, near, or along its sides compared to at, near, or along its centre.

The wrap is preferably about six times longer than it is wide, most preferably with a slimmed region at or near its longitudinal midpoint. The wrap desirably includes one or more, preferably two, longitudinal slits near its thinned region to allow the wrap to conform radially more closely with the inner curve of the aorta. The wrap is preferably shaped to allow good conformance with the curved aorta – the slits allow improved conformity. The wrap preferably also includes an opening for a fluid tube.

In another embodiment, the wrap may be coated with a material to reduce its surface area and to limit tissue ingrowth. The wrap is preferably coated on one or both sides with either silicone or polyurethane or a co-polymer of both.

In another embodiment the wrap may be of an open weave structure (such as by gauze weaving using a leno weave) or a mesh, to allow vascular ingrowth from external to the wrap to provide nourishment of the outer wall of the aorta. The slits on the inner curvature of the wrap may also achieve this, as may further slits circumferentially on the lateral or outer curvature aspects of the wrap.

Brief Description of the Drawings

Preferred embodiments of the present invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

Fig. 1 is a top view of a first embodiment of a wrap according to the invention;

Fig. 2 is a perspective view of the wrap shown in Fig. 1;

Fig. 3 is a schematic cross-sectional view of a prior art wrap around an aorta;

Fig. 4 is a schematic cross-sectional view of the wrap shown in Fig. 1 around an aorta;

Fig. 5 is a partial top view of a second embodiment of a wrap according to the invention; and

Fig. 6 is a partial top view of a third embodiment according to the invention.

Detailed Description of the Preferred Embodiment

Referring firstly to Fig. 1 and 2, there is shown a wrap 20 according to a first embodiment of the invention. The wrap 20 is produced from woven polyester or similar non-absorbable biostable and biocompatible material and includes ends 22, 24 and sides 26, 28.

The wrap 20 includes an opening 30 for a fluid tube to be connected to, for example, the inflatable balloon or chamber (not shown) of a heart assist device. The wrap 20 also includes a thinned region with a pair of curved longitudinal slits 32, which serve to prevent the wrap from kinking or folding when it is wrapped around a curved portion of aorta.

About two-thirds of the sides 26, 28 of the wrap 20 include a series of spaced apart slits 34 which are substantially normal to the longitudinal axis of the wrap 20. These slits 34 results in those parts of the sides 26, 28 of the wrap 20 being more elastic or stretchable than the intermediate central portion of the wrap 20. As a result, when the wrap 20 is placed around a section of aorta and tightened to a snug fit, less tension is placed in the sides 26, 28 or edges of the wrap 20 than in the centre. This avoids the depression/kinking, and associated high strain levels, associated with known wraps (as was discussed in relation to Fig. 3).

A schematic illustration of the wrap 20 around a section of aorta 36 is shown in Fig. 4. The regions 38 of the aorta 36 adjacent the sides 26, 28 of the wrap have a smooth curved transition from a larger to smaller diameter. These curved transition regions 38 result in less strain in the wall of the aorta 36, which reduces the chance of damage to same. The curved transition zones 38 also reduce turbulence in the blood flow through the aorta 36 and thereby reduce the likelihood of plaque formation.

A second embodiment of wrap 40 is shown in Fig. 5. In this embodiment, the wrap 40 according to the invention is again of woven polyester construction with longitudinal warp fibres 42 and lateral weft fibres 44. In the wrap 40, the warp fibres 46 adjacent the sides of the wrap 40 are made crimped which makes them more elastic or stretchable than the un-crimped warp fibres 48 in the centre of the wrap 40.

Fig. 6 shows another embodiment of wrap 50 according to the invention which is again of woven polyester construction. The wrap 50 includes a second polyester strip 52

attached to its centre. The strip 52 has a tensile strength greater than that of the rest of the wrap 50 which results in the sides 54, 56 being more elastic or stretchable than the centre 52.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications can be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly defined.